Status of the Claims

Claims 1, 2, 6-15, and 17-20 remain pending. Claims 3, 4, 16, and 21-22 were previously cancelled in response to a Restriction Requirement. Claims 1 and 12 have been amended. No new matter has been added by way of amendment.

Remarks

Applicants propose to amend claims 1 and 12. Applicants propose to limit the scope of claims 1 and 12 to a single lumen catheter per the suggestion of the Examiner, merely to move the present application towards allowance, and with no acceptance of the Examiner's position, which applicants maintain is contrary to M.P.E.P. Section 211.03. Applicants also reserve the right to pursue the subject matter in a later application.

The Rejections Under 35 U.S.C. §103(a) Should be Withdrawn

The Examiner has maintained the rejection of claims 1, 2, 5-15, 17-20 under 35 U.S.C. 103(a) as being unpatentable over Love et al. (USP 6,221,622) and Makita et al. (Breast Cancer Research, 1991), in view of Sukumar et al. (USP 5,763,415), King et al. (JNCI, 1983), Noguchi et al. (American Journal of Pathology, 1994), Gross G. (Intervirology, 1997), and Androphy (Ciba Found, Symposium, 1986). The Applicant traverses this rejection.

The examiner previously stated that the present claims containing the claim limitation "comprising an elongated lumen" does not "...narrow the claim [to] a single lumen catheter." Per the Examiner's suggestion, the Applicant has amended claims 1 and 12 to read on a single lumen catheter.

The Examiner also has stated that "[t]he Love *et al.* reference still applies even if the claims were limited to a single lumen catheter because the reference teaches the use of a syringe to wash the breast duct." The Applicant respectfully disagrees. Love *et al.* only mentions the use of a syringe to wash a breast duct through the lumen of a dual-lumen catheter. Nowhere in Love *et al.* is there a description of a single lumen catheter being used as the primary device to irrigate and remove fluid from a single breast duct. The Examiner states that the Love *et al.* reference "...teaches that the Love and Barsky prior art reference uses a single lumen catheter and that the prior art reference contemplated the double lumen catheter but did not actually use such a catheter in the reference." The Examiner then goes on to state that "[t]he purpose of the Love *et al.* patent was to improve over the prior art by using a double lumen catheter indicating that the prior art only included the single elongated lumen catheter." The Applicant strongly disagrees.

The argument by the Examiner that Love *et al.* "teaches" by making reference to secondary art is improper. To establish a *prima facie* case of obviousness includes the criteria that all of the limitations of the claims must be taught or suggested by the prior art. *In re Royka* 490 F.2d 981 (CCPA 1974). The statement that the Love and Barsky reference teaches the use of a single lumen catheter because the double lumen catheter, specifically taught in Love *et al.*, is a necessary improvement over Love and Barsky, is mere speculation put forth by the Examiner. To establish a *prima facie* case of obviousness includes the criteria that all of the limitations of the claims must be taught or suggested by the prior art cited by the Examiner (e.g., Love *et al.*) not a secondary reference. The Examiner has not cited Love and Barsky against the claims of the present invention, nor has the Examiner proffered any proof that Love and Barsky teaches or suggests a single lumen catheter. Thus, the Examiner has not established a *prima facie* case of

obviousness because Love et al. does not teach or suggest a single lumen catheter being used as the primary device to irrigate and remove fluid from a single breast duct.

The Examiner further states that Makita *et al.* "...teaches the aspiration of ductal fluid/sample using an outer cylinder, the 'outer' cylinder when aspirating the sample is a single elongated lumen present in the breast duct." The Applicant respectfully disagrees with the Examiner's characterization of Makita *et al.* Makita *et al.* does not teach the aspiration of ductal fluid. Makita *et al.* teaches obtaining a biopsy of tissue with an endoscope. Thus, Makita *et al.* cannot be used to teach the use of a single lumen catheter to wash and collect fluid from a single breast duct. An endoscope is not a device capable of injecting and then retrieving fluid from a breast duct. Thus, Makita *et al.* does not teach or suggest, either alone or in combination, all of the limitation of the claim of the present invention.

Lastly, as related to King *et al.*, the Examiner argues that, even though there is no support in King *et al.* for the examination of HPV in ductal fluid, King *et al.* is still relevant as prior art because "...the instant specification does not limit ductal fluid to the liquid portion." However, on page 3, lines 13-15, the Examiner argues that the Applicant's previous arguments are not convincing because "limitations from the specification are not read into the claims." See *In re Van Geus*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed Cir. 1993). The Examiner cannot have it both ways.

Even assuming *arguendo* that the limitations from the Applicant's specification may be read into the claims to include the detection of viral particles in cells found in ductal fluid, King *et al.* still does not establish that papillomavirus can be detected in fluid samples obtained from breast ducts.

As mentioned previously, Table 5 of King et al describes histologic types of breast disease tissues, not breast fluid or cells from breast fluid (see page 2, column 1, lines 3-10). The histological types described in table 5 come from tissues subsequently collected from biopsies or mastectomies, not from the washing of the breast ducts. Thus, King et al fails to teach a method for identifying or treating a patient having an increased risk for developing breast precancer or breast cancer by retrieving a ductal fluid sample from within the breast duct and detecting a viral agent in the ductal fluid sample. There is no teaching in any of the other cited references of detecting a viral agent in a ductal fluid sample.

For all of the above-discussed reasons, Applicant submits that all grounds of rejection under 35 U.S.C. §103(a) have been overcome. Withdrawal of the rejection is requested.

Applicant respectfully submits that claims 1, 2, 5-15, 17-20 are allowable and that the application is now in condition for allowance.

In addition, all amendments set forth above would raise no new issues that would require further consideration and/or search. Applicants submit that these amendments would place the claims into condition for allowance, or at least present the rejected claims in better form for consideration on appeal, and should therefore be entered after the final rejection under 37 C.F.R. 1.116 (a).

Conclusion

In light of the arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper.

However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.001911.

Respectfully submitted,

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